

REMARKS

I. STATUS OF CLAIMS

Claims 1-4, 7-8, 10, 12 and 18 have been amended. Support for the addition to claim 1 is found at least in paragraph [0088]. Claims 5-6, 11, 19-56 have been cancelled, though applicants reserve the right to pursue the claimed subject matter in one or more continuing applications. Upon entry of this response, therefore, claims 1-4, 7-10 12-18 will be pending.

Applicants respectfully request reconsideration of the application in view of the foregoing amendments and these remarks.

II. REJECTIONS UNDER 35 U.S.C. § 112 ¶1

The examiner rejects claims 1-28, 37, 38, 41, 42, 50 and 51 for an alleged lack of written-description and enablement support, respectively. Applicants traverse the rejection.

In particular, applicants showed that measuring the levels of galectin-3 and fibrinogen provides an effective means for qualifying the severity of a subject's myocardial infarction. In view of the specification's commentary and supporting data, an artisan reviewing the application would recognize readily that applicants possessed the claimed invention at the time of filing, in satisfaction of the "written description" requirement of §112. Moreover, in view the specification's guidance and examples, the skilled person could have implemented the claimed methodology with only routine (not "undue") experimentation. Thus, the "enablement" requirement of §112 is met, too. Applicants request, therefore, that the rejections be withdrawn.

III. REJECTIONS UNDER U.S.C. § 112 ¶2

The examiner rejects claims 1-23, 27-45, 48-51 and 54-56 for alleged indefiniteness. Applicants believe the amendments entered herein obviate the rejections and, therefore, request their withdrawal.

IV. REJECTIONS UNDER U.S.C. § 102

The examiner rejects claims 1-5, 7, 11, 12, 16-19, 22-24, 27-31 and 45 under § 102(e) for alleged anticipation by Prolla *et al.* Claims 1-5, 7, 11, 16, 19, 22, 24, 27, 29-31 and 45 also are rejected under § 102(b) over Nachtigal *et al.* Finally, claims 19, 22-24, 27-31 and 45 are said to lack novelty in view of Liu *et al.* Applicants respectfully traverse these rejections.

Prolla is cited for teaching assays for measuring the biological age of multicellular organisms, where such assays involve detecting galectin-3, among other things. Meanwhile, Nachtigal is cited for antibody-based detection of galectin-3 in samples from patients with atherosclerosis, and Liu is cited for teaching detection of galectin-3 generally in human monocytes and macrophages.

The cited material, however, says nothing of using galectin-3 to qualify the severity of myocardial infarction or even of ischemic heart disease in general. Further, there is no teaching in any cited reference that would prompt the skilled person to employ galectin-3 as a marker for a subject who has suffered a myocardial infarction. Thus, Prolla, Nachtigal and Liu each fail to teach every element of the claimed methodology. None of the cited documents can anticipate the claims, therefore, and the rejections should be withdrawn.

V. REJECTIONS UNDER U.S.C. § 103

The examiner rejects claims 1-5, 7-19, 22-24, 27-37, 43-47 and 52-55 over the combination of Prolla in view of Issaq and Liu. Claims 1-7, 11, 16, 19-22, 24-27, 29-31, 33, 34, 36, 37, 39, 40, 42, and 45 also are rejected over Nachtigal and Bini *et al.* Applicants respectfully traverse the rejection.

The deficiencies of Prolla, Liu, and Nachtigal are discussed above. Issaq, cited for teaching the use of SELDI-TOF mass spectrometry in conjunction with protein chips, and Bini, cited for teaching immunohistochemical detection of fibrinogen, fail to cure the inadequacies of the primary references. Thus, no combination of the cited documents could have led the skilled artisan to applicants' claimed invention. In the absence of a *prima facie* case of obviousness, applicants therefore request withdrawal of these rejections.

Applicants submit that this application is in condition for allowance, and they request an early indication to this effect. Examiner Grun also is invited to contact the undersigned directly, should he feel that any point warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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